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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/097,791 06/16/98 BOYCE-JACINO

M 13065

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HM22/0321

EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

03/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/097,791

Applicant(s)

Boyce-Jacino et al.

Examiner

Ardin Marschel

Group Art Unit
1631



☒ Responsive to communication(s) filed on Jan 13, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-30 is/are pending in the application

Of the above, claim(s) 29 and 30 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-30 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~Page 1013~~ (4 sheets)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' election with traverse of Group I (claims 1-28) in Paper No. 8, filed 1/13/00, is acknowledged. The traversal is on the ground(s) that there would not be a serious search burden if the restriction is not required and that public interest would be served by not issuing two patents on the same invention. This is not found persuasive because separate publications generally are directed to sequencing versus other forms of analysis such as DNA fingerprinting, target nucleic acid detection, etc. wherein an array may be or may not be utilized. Thus, searching for references that describe an array as given in Group II would vastly proceed beyond the single usage type being sequence analysis as given in Group I. Thus, a serious search burden would result in performing a prior art search for both of Groups I and II together contrary to the allegation of applicants. This was already summarized in the previous office action, mailed 7/7/99, and has not been negated by alleging otherwise. Secondly, regarding the second argument, a patent for a method of sequence analysis and a patent for arrays are two patents for two distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because no submission of computer readable form sequences etc. has been submitted. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. For example, page 35 of the specification contains sequences which fall under this rule.

Claim 2 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite as to whether the primer therein cited is limited to 3-7 bases or is limited by being at least 3-7 bases but including longer primer practice because of the open claim language term "comprises" in line 1. In other words, it is unclear whether the "comprises" word limits the primer length or the 3-7 bases limitation. Clarification via clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-27 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Cantor et al. (P/N 5,795,714).

Cantor et al. utilizes a variety of techniques for sequence analysis as summarized in column 6, line 38, through column 18, line 4. One is disclosed in column 17, line 32, through column 18, line 4, wherein an array is utilized for capture of a target nucleic acid via hybridization of a complementary sequence. The complementary sequence is then extended as a primer by polymerase followed by detection and analysis of the sequence of the target. Primer and polymerase must inherently complex for the formation of an extension product as required in the instant claims. It is noted that the reference in column 12, lines 57-63, and column 17, lines 19-51, cites various lengths of probes etc. but that instant claim 2 is unclear as to what length is required therein as explained in the above rejection under 112, second paragraph. A pattern of signals are analyzed in column 17, lines 24-31, as also required in instant claim 3. It is noted that the probe/primers on the arrays contain both a single and double stranded region wherein the double stranded region cannot hybridize to the target but serves as the spacer of instant claim

4 and these segments serve as probes, capture reagents, and/or primers as required in instant claims 13-15 and 17. Various solid supports are cited with attachment moieties in column 12, lines 62-67; column 17, lines 51-53; and column 20, line 66, through column 21, lines 1-9; which anticipate instant claims 5-10 and 12. Specific 5' end attachment is cited in column 19, lines 34-40, as also required in instant claim 11. The inclusion of PCR primer sequences as required in instant claim 16 is exemplified in column 32, lines 55-60, and summarized in the abstract. Various nucleotide analogues as well as labels as well as various sequencing methodologies as cited in instant claims 18-27 are disclosed in the examples in the reference as well as in column 6, line 51, through column 9, line 50. These disclosures anticipate the above listed instant claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed

invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cantor et al. (P/N 5,795,714) in view of Pease et al. (Ref CB).

Cantor et al. has been summarized above regarding the limitations of instant claims 1-27 but lacks disclosure of high density arrays as required for the practice of instant claim 28. Cantor et al., however, generically suggests and motivates array practice for screening target sequences throughout the disclosure, for example, at column 8, lines 31-67, etc.

Pease et al. describes the synthesis of an increased density array therein and also suggests and motivates the reasonable expectation of success for the preparation and use of even higher density arrays in the Discussion section on pages 5025-5026 which are inclusive of densities within the scope of instant claim 28 for usage as desired in methods that utilize hybridization to arrays of polynucleotides.

Thus, it would have been obvious to someone of ordinary

skill in the art at the time of the instant invention to practice the high density arrays as an embodiment within the scope of instant claim 1-28 because Cantor et al. describes the basic polymerase based primer methodology of the instant invention and indicates or suggests that arrays as known in the prior art are usable for that method and Pease et al. further motivates and suggests high density array practice for hybridization based sequence analysis.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

March 17, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER